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10/827,485	04/19/2004	Makarand P. Gore	200315628-1	3286

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EXAMINER	
MERCIER, MELISSA S	
ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
03/08/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/827,485	GORE, MAKARAND P.	
	Examiner	Art Unit	
	MELISSA S. MERCIER	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,9-15,17-24 and 26-49* is/are pending in the application.

4a) Of the above claim(s) *19-44 and 47-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,9-15,17,18,45 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of Applicants Remarks and Amended Claims filed on December 10, 2009 is acknowledged. Claims 1-5, 9-15, 17-24, 26-49 remain pending in this application. Claims 19-44 and 47-49 remain withdrawn and Claims 1-5, 9-15, 17-18, and 45-46 remain under prosecution.

Withdrawn Rejections/Objections

Claim Rejections - 35 USC § 112

The rejection of claims 1 and 45 because it was unclear what “configured to be dispensed” encompasses in terms of structural limitations has been withdrawn in view of Applicants amendment to the claims to remove the phrase.

The rejection of claim 3, because it was unclear if the pharmaceutically active ingredient is limited to the Markush group presented of if additional active ingredients can be added in has been withdrawn in view of Applicants amendment to the claim to recite "selected from the group consisting of" as suggested by the Examiner.

The rejection of claim 17, because it is unclear what Applicants is claiming by “a pharmaceutical release rate of said solution is varied by varying said naturally occurring oil". It is unclear what the metes and bounds of “varied by varying” are has been withdrawn in view of Applicants amendment to the claim to recite “a pharmaceutical release rate of said solution is selectively adjusted by varying the type of said oil”.

The rejection of claim 18, because it is unclear what part of the jet table solution is the pharmaceutically active ingredient since according to claim 1, it is a required component, however, claim 18 does not accommodate for it in the percentages has been withdrawn in view of Applicants arguments regarding the active agent can be present up to 15% of the total composition.

Maintained Rejections/Objections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 10, and 15 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claims 3 and 10, M.P.E.P. § 2163 states, “An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention...one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not

permit one skilled in the art to immediately envisage the product claimed from the disclosed process."

The specification does not describe any species of the instantly claimed derivatives of a water insoluble peptide, an antimicrobial, a PPI, a calcium channel blocker, a beta blocker, an anesthetic, a steroid, an antioxidant, a rennin inhibitor, an alkaloid, a cystostatica, an anti coagulant, a lipid regulating agent, an antidepressant, a neuroleptic, an immunosuppressant, an immunomodulator, an antibiotic, an anti-inflammatory agent, nicotinaminde derivatives at p. 11, therefore, it does not describe a sufficient number of species as to convey possession of the entire genus encompassed by derivatives thereof.

Regarding claim 15, Applicant has not provided adequate written description for "a non-acrylic polymer". After a review of the specification, the Examiner was unable to locate any species of polymers that Applicant feels would provide adequate written description for the very broad claim of "a non-acrylic polymer". If Applicant believes such support exists, they are invited to identify such support in the specification as originally filed.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues:

***One skilled in the relative art would readily understand that composition of the derivatives of the various pharmaceuticals and surfactants of the instant claims.**

The Examiner respectfully disagrees. The specification does not disclose even one example of what would be encompassed by derivatives' thereof or by the term non-acrylic polymers. The skilled artisan has not direction or guidance as to what would be considered to be derivatives of any of the cited components. Applicant also has not demonstrated that every type of polymer would be capable of providing the appropriate results with the scope of the invention. The specification does not provide any guidance as to what derivatives would be acceptable in the composition.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 10, Applicant has amended the claim to remove the terminology "such as" but has replaced it with "including". It is unclear if Applicant is limiting the aromatic sulfonate salts to the cited salts or if they are listed as explanatory and not limiting in nature.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues:

***it is clear that the aromatic sulfonate salts include one of those aromatic sulfonate salts include one of those aromatic sulfonate salts recite thereinafter.**

The Examiner respectfully disagrees. While it acknowledged that the salts recited are sulfonate salts, the claim language utilized do not restrict the salts to only those listed. It is suggested that Applicant amend the claims to recite “selected from the group consisting of…".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 9-10, 13-15 and 45-46 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Dennis et al. (US Patent 6,623,765).

Dennis discloses micro emulsions and micelle systems for solubilizing drugs (title). A micro emulsion delivery system for water insoluble or sparingly soluble drugs that comprise a long polymer chain surfactant component and a short fatty acid surfactant component (abstract). The microemulsiion systems, particularly oil and water, can be used to dissolve substantial concentrations of oil soluble drugs, such as propofol (column 3, line 65 through column 4, line 2).

Regarding claims 2-3, suitable drugs include analgesics, anesthetics, anti-asthmatics, antidiabetics, antifungal, antihypertensives, anti-inflammatories, for example (columns 4-7).

Regarding claim 10, suitable examples of long chain surfactants include lecithin and tweens (column 8, lines 40-64).

Regarding claim 14, salts of lidocaine or tetracaine can also be included (column 10, lines 43-46).

While the reference does not disclose the viscosity or the surface tension of the solution, is it the position of the Examiner that in the absence of a showing otherwise, the composition of Dennis possesses the claimed physical properties.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues:

***there is no teaching of the viscosity claimed.**

While it is acknowledged that Dennis does not specifically disclose the viscosity, Owen does disclose the same components, in the same amounts and absent a showing of evidence to the contrary, would inherently possess the same properties such as viscosity. Applicant has not provided any evidence to the showing the viscosity is different.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 10, 13-15, 17, and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barreto (US Patent 7,166,154).

Barreto disclose an ink in a jettable vehicle, wherein the ink is edible (abstract). The vehicle imparts a jettable viscosity (column 4, lines 39-40). The solvent comprises water (column 4, lines 44-45). The vehicle can further comprise reducing oils and solvents (column 5, lines 53-55). Antioxidants can be also be included (column 5, line 56), which Claim 3 discloses as a suitable pharmaceutically active agent. Depending on the particular antioxidant selected would determine its location within the emulsion (i.e. water soluble or oil soluble). Surfactants, including lecithin and tween, are disclosed as emulsifiers (column 5, lines 3-5), thereby meeting the limitation of claim 10.

Regarding claim 14, Colorants, including quinine sulfate and riboflavin phosphate, both of which are salts, are also included (claim 57).

Regarding claims 15, other additives including humectants, waxes, lubricants, body gums and binding varnish, resins, and binders can be incorporated into the solution (column 5, lines 50-55).

Barreto does not explicitly disclose the solution comprises a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 and 60 dynes per centimeter. However, since the composition disclosed by Barrett comprises the same components as the instant claims and is used for an identical purpose, the physical properties of viscosity and surface tension are necessarily also present or well within the skilled artisan's knowledge to optimize for the intended function. The specification on page 3-4 defines jettable as any material that has properties sufficient to allow the material to be selectively deposited by any digitally addressable inkjet material dispenser. The USPTO does not possess laboratory facilities, therefore, since Barreto discloses the same composition, the burden shifts to Applicant to provide evidence that the prior art formulation does not possess the same physical properties as the instant claims.

Barreto does not require the solution be an emulsion. However, based on the disclosure of Barreto in which oils are optional components, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have prepared the ink as an emulsion based on the suggestion by Barreto.

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barreto (US Patent 7,166,154) in view of Woo (Formulation and physicochemical properties of macro- and micro emulsions prepared by interfacial ion-pair formation between, see IDS).

The teachings of Barreto are discussed above and applied in the same manner.

Barreto does not teach the use of or amount to use of a surfactant comprising an ion-pair formation between an amino acid and a fatty acid, wherein the amino acid comprises L-arginine or L-lysine and the fatty acid comprises stearic acid or oleic acid.

Woo teaches that water-in-oil and oil-in-water emulsions can be prepared using stearic acid and L-arginine or L-lysine (pg. 105-109).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the components taught by Woo to emulsify the composition taught by Barreto because these naturally occurring fatty acids and amino acids are extremely safe and ideal for pharmaceutical use (Woo, pg. 103). Furthermore, determining result effective amounts of the ingredients beneficially taught by the cited references is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the ordinary artisan.

Response to Arguments

It appears Applicant is attempting to invoke the 103(c) shield. This must be explicitly stated on the record.

Newly Applied Rejections/Objections

Claim Rejections - 35 USC § 102/ 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5, 13-15, and 45-46 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Owen et al. (US Patent 5,633,226).

Owen discloses water in oil micro emulsion which readily converts to oil in water emulsion by addition of aqueous fluid to the water in oil micro emulsion (abstract).

The biologically active material composition comprises:

1. an aqueous phase;

2. a pharmaceutically acceptable oil;

3. an oil dispersible surfactant;

4. a water soluble biologically active material;

Additional adjuvant such as stabilizers, coloring agents (claim 15), oil soluble drugs (claim 2) and the like may be added. Each component is disclosed as being suitable for use in the subject and will usually be food grade and/or pharmaceutically acceptable (column 4, lines 49-59).

The water in oil micro emulsions can be liquids at room temperature (column 5, lines 9-11).

The aqueous phase ranges up to 60% by volume, the oil phase is from about 5-99% by volume, and the surfactant is present from about 1-70% by volume (column 5, lines 16-19).

Regarding claim 5, the oil can include edible oils, such as coconut oil (column 6, lines 27-35).

Regarding claims 13-14, the aqueous phase may comprise other solvents, such as polyhydrolic alcohols, glycerol, and propylene glycol (column 5, lines 45-48). Salts can also be present, such as when saline is employed.

Owen does not explicitly disclose the solution comprises a viscosity of less than approximately 5 centipoise and a surface tension approximately between 25 and 60 dynes per centimeter. However, since the composition disclosed by Owen is identical in components and percentages within the dependent claims, the physical properties of viscosity and surface tension are inherently also present. However, if they are not inherently present, it is well within the skilled artisan's knowledge to optimize for the intended function. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have optimized the composition of Owen because he discloses his composition can be in different forms, such as solids and semi solids, he additionally exemplifies all forms, thereby showing he was in possession of the entire scope of his invention including the solution form. The specification on page 3-4 defines jet table as any material that has properties sufficient to allow the material to be selectively deposited by any digitally addressable inkjet material dispenser.

The USPTO does not possess laboratory facilities, therefore, since Owen discloses the same composition, the burden shifts to Applicant to provide evidence that the prior art formulation does not possess the same physical properties as the instant claims.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues:

***there is no teaching of the viscosity claimed.**

While it is acknowledged that Owen does not specifically disclose the viscosity, Owen does disclose the same components, in the same amounts and absent a showing of evidence to the contrary, would inherently possess the same properties such as viscosity. Applicant has not provided any evidence to the showing the viscosity is different.

***Owen does not teach water insoluble drugs.**

This argument is persuasive. Therefore claim 2 has been removed from the rejection.

***Owen does not disclose the release rate can be varied by varying the type of oil.**

This limitation is considered to be a functional property. Therefore, absent a showing of evidence to the contrary, the functional property would inherently be present.

Claim Rejections - 35 USC § 103

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Owen et al. (US Patent 5,633,226) in view of Woo (Formulation and physicochemical properties of macro- and micro emulsions prepared by interfacial ion-pair formation between, see IDS).

The teachings of Owen are discussed above and applied in the same manner.

Owen does not teach the use of or amount to use of a surfactant comprising an ion-pair formation between an amino acid and a fatty acid, wherein the amino acid comprises L-arginine or L-lysine and the fatty acid comprises stearic acid or oleic acid.

Woo teaches that water-in-oil and oil-in-water emulsions can be prepared using stearic acid and L-arginine or L-lysine (pg. 105-109).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the components taught by Woo to emulsify the composition taught by Owen because these naturally occurring fatty acids and amino acids are extremely safe and ideal for pharmaceutical use (Woo, pg. 103). Furthermore, determining result effective amounts of the ingredients beneficially taught by the cited references is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the ordinary artisan.

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dennis et al. (US Patent 6,623,765) in view of Woo (Formulation and physicochemical

properties of macro- and micro emulsions prepared by interfacial ion-pair formation between, see IDS).

The teachings of Dennis are discussed above and applied in the same manner.

Dennis does not teach the use of or amount to use of a surfactant comprising an ion-pair formation between an amino acid and a fatty acid, wherein the amino acid comprises L-arginine or L-lysine and the fatty acid comprises stearic acid or oleic acid.

Woo teaches that water-in-oil and oil-in-water emulsions can be prepared using stearic acid and L-arginine or L-lysine (pg. 105-109).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the components taught by Woo to emulsify the composition taught by Dennis because these naturally occurring fatty acids and amino acids are extremely safe and ideal for pharmaceutical use (Woo, pg. 103). Furthermore, determining result effective amounts of the ingredients beneficially taught by the cited references is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the ordinary artisan.

Conclusion

Due to the new grounds of rejection presented in this office action, this action is made Non-Final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is

(571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/Carlos A. Azpuru/
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